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PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application:

Harold I. NYLAND et al	Conf. No.: **8578**
Serial No.: **09/599,002**	Group Art Unit: **1655**
Filed: **June 22, 2000**	Examiner: **Johannsen, D.**

For: **METHOD FOR DISEASE DIAGNOSIS BASED ON Fc RECEPTOR GENOTYPING**

RESPONSE TO RESTRICTION REQUIREMENT

Assistant Commissioner
of Patents
Washington, D.C. 20231

Sir:

This Response to Restriction Requirement is in reply to the Office Action dated July 18, 2001, in the above-identified application, for which a Petition for a Two-Month Extension of Time, along with payment of the appropriate fee, is attached, making reply due on or before October 18, 2001.

The Patent Office is authorized to charge any fees necessary for the continued pendency of the above-identified application to our Deposit Account No. 19-4880.

Accordingly, please amend the above-identified application as follows.

IN THE CLAIMS:

Please cancel Claims 1-14.

Please add the following new claims:

-- Claim 15. A method comprising the steps of:

(a) determining, as a genetic marker, the genotype of DNA encoding at least one Fc receptor, wherein said DNA is obtained from a test mammalian subject; and

(b) comparing the thus determined genotype to the genotype of DNA encoding an Fc receptor obtained from a normal mammalian subject or the genotype of DNA encoding an Fc receptor obtained from a diseased mammalian subject, wherein said diseased mammalian subject is a mammalian subject afflicted with a disease selected from the group consisting of multiple sclerosis, myasthenia gravis, diabetes mellitus, cerebrovascular disease, cardiovascular disease, atherosclerosis and Addison's disease,

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wherein when the determined genotype for the DNA obtained from the test mammalian subject corresponds to the genotype of DNA obtained from said normal mammalian subject, a benign prognosis is made for the test mammalian subject; and

wherein when the determined genotype of DNA obtained from the test mammalian subject corresponds to the genotype of DNA obtained from said diseased mammalian subject, a non-benign prognosis is made for the test mammalian subject.

Claim 16. The method of Claim 15, wherein said Fc receptor is an Fcγ receptor.

Claim 17. The method of Claim 16, wherein said Fcγ receptor is FcγRIIA, FcγRIIIB or a combination thereof.

Claim 18. The method of Claim 15, wherein when said disease is multiple sclerosis, and said determined genotype is FcγRIIA H/H, FcγRIIIB NA1/NA1 or a combination thereof, said prognosis is a benign prognosis.

Claim 19. The method of Claim 15, wherein when said disease is myasthenia gravis, and said determined genotype is FcγRIIIB NA1/NA1, said prognosis is a non-benign prognosis; and wherein when said disease is myasthenia gravis, and said determined genotype is FcγRIIA R/R, FcγRIIIB NA2/NA2 or a combination thereof, said prognosis is a benign prognosis.

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Claim 20. The method of Claim 15, wherein when said disease is diabetes mellitus, and said determined genotype is FcγRIIIB NA1/NA1, FcγRIIA H/H or a combination thereof, said prognosis is a non-benign prognosis.

Claim 21. The method of Claim 15, wherein when said disease is cerebrovascular disease, cardiovascular disease, or atherosclerosis, and said determined genotype is FcγRIIIB NA2/NA2, said prognosis is a non-benign prognosis.

Claim 22. The method of Claim 15, wherein when said disease is Addison's disease, and said determined genotype is FcγRIIA H/H, said prognosis is a non-benign prognosis.

Claim 23. The method of Claim 15, wherein said method further comprises the step of:

(c) determining the presence or absence of a genetic marker for susceptibility to said disease in the test mammalian subject.

Claim 24. The method of Claim 15, wherein when a non-benign prognosis is made, said method further comprises the step of:

(c) subjecting the test mammalian subject to diagnostic imaging.

Claim 25. The method of Claim 15, wherein when a non-benign prognosis is made, said method further comprises the step of:

(c) subjecting the test mammalian subject to surgical intervention against said disease.

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Claim 26. The method of Claim 15, wherein when a non-benign prognosis is made, said method further comprises the step of:

(c) administering, to the test mammalian subject, a prophylactically or therapeutically effective amount of a prophylactic or therapeutic material against said disease.

Claim 27. The method of Claim 23, wherein when a non-benign prognosis is made and the presence of said genetic marker for susceptibility to said disease is found in the test mammalian subject, said method further comprises the step of:

(d) administering, to the test mammalian subject, a prophylactically or therapeutically effective amount of a prophylactic or therapeutic material against said disease.

Claim 28. The method of Claim 23, wherein said method further comprises the step of:

(d) subjecting the test mammalian subject to diagnostic imaging.

Claim 29. The method of Claim 23, wherein said method further comprises the step of:

(d) subjecting the test mammalian subject to surgical intervention against said disease.

Claim 30. A diagnostic method comprising the steps of:

(a) obtaining test DNA from a test mammalian subject, wherein said test DNA encodes at least one Fc receptor;

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(b) determining the genotype of thus obtained test DNA; and

(c) comparing the thus determined genotype to the genotype of DNA encoding an Fc receptor obtained from a normal mammalian subject or the genotype of DNA encoding an Fc receptor obtained from a diseased mammalian subject, wherein said diseased mammalian subject is a mammalian subject afflicted with a disease selected from the group consisting of multiple sclerosis, myasthenia gravis, diabetes mellitus, cerebrovascular disease, cardiovascular disease, atherosclerosis and Addison's disease,

wherein when the determined genotype of the test DNA corresponds to the genotype of DNA obtained from said diseased

mammalian subject, said test mammalian subject is diagnosed with said disease.

Claim 31. The method of Claim 30, wherein said method further comprises the step of:

(d) determining the presence or absence of a genetic marker for susceptibility to said disease in the test mammalian subject.

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Claim 32. The method of Claim 15, wherein said genotype is determined using an Fc receptor allele-specific binder.

Claim 33. A kit for prognosis of disease comprising:

(a) at least one Fc receptor allele-specific binder; and

(b) instructions for preparing a prognostic assay employing the same.

Claim 34. The kit of ~~Claim~~ 33, wherein said Fc receptor is an Fcγ receptor.

Claim 35. The kit of Claim 34, wherein said Fc receptor is FcγRIIA, FcγRIIIB or a combination thereof. --

REMARKS

Initially, Applicants hereby cancel all of the pending claims and substitute therefor new Claims 15-35, support for which can be found, *inter alia*, in cancelled Claims 1-14, and the Examples provided in the present specification. Hence, new Claims 15-35 do not constitute new matter, and thus entry is requested.

On page 2 of the Office Action, the Examiner has issued a Restriction Requirement under 35 U.S.C. § 121 to one of the inventions of the following groups:

Group I - Claims 1, 3, 5 and 7-13, directed to a methods of disease prognosis;

Group II - Claims 2, 4 and 7-13, directed to a methods of prophylaxis or therapy;

Group III - Claims 6-13, directed to methods of manufacture; and

Group IV - Claim 14, directed to a kit.

Accordingly, Applicants hereby elect the invention of Group I (new Claims 15-32). In view of the new claims presented herein, restriction as between the claims of Groups I, II and III has been rendered moot. Further, in view of the new claims presented herein, the Examiner is requested to reconsider and withdraw the restriction requirement with respect to the kit claims of Group IV (new Claims 33-35), as they all have a common feature with the elected invention of Group I.

The Examiner is invited to contact the undersigned at his Washington telephone number on any questions which might arise.

Respectfully submitted,

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